DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: REDUX™
Docket No. 96E-0265

FEB 18 1997

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FEB 21 1997

PATENT EXTENSION
A/C PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,309,445, filed by Interneuron Pharmaceuticals, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for REDUX™, the human drug product claimed by the patent.

The total length of the regulatory review period for REDUX™ is 1,613 days. Of this time, 541 days occurred during the testing phase and 1,072 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 1, 1991.

   The applicant claims January 13, 1992, as the date the Investigational New Drug application (IND) for REDUX™ (IND 38,108) became effective. However, FDA records indicate that the effective date for IND 38,108 was December 1, 1991, which was thirty days after FDA receipt of the IND on November 1, 1991.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: May 24, 1993.

   The applicant claims May 23, 1993, as the date the New Drug Application (NDA) for REDUX™ (NDA 20-344) was initially submitted. However, FDA records indicate that NDA 20-344 was submitted on May 24, 1993.

3. The date the application was approved: April 29, 1996.

   FDA has verified the applicant's claim that NDA 20-344 was approved on April 29, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Charles E. Vann Horn
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